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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/960,720	09/21/2001	James Clagett	48968 CON	4192
21874	7590	02/12/2004	EXAMINER	
EDWARDS & ANGELL, LLP			ROBINSON, HOPE A	
P.O. BOX 55874			ART UNIT	
BOSTON, MA 02205			PAPER NUMBER	
			1653	
DATE MAILED: 02/12/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/960,720

Applicant(s)

CLAGETT, JAMES

Examiner

Hope A. Robinson

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 March 2002.  
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☐ Claim(s) 1-12 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

***Specification***

1. The disclosure is objected to because of the following informalities:

The specification is objected to because on page 5, line 27, the word "mammals" is misspelled as "mamals".

Correction is required.

***Abstract***

2. The abstract of the disclosure is objected to because line 1 discloses "Methods for treating treating fibrosis..." .

Correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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3. Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

For clarity claim 1 should be amended to recite "comprising" where the claim recites " A method for treating fibrosis in a mammal comprises administering" and should recite the spelled out meaning of the acronym "f-Met-Leu" (N-formyl-methionyl-leucyl). Claim 1 is indefinite because the claim does not recite time, conditions and outcome of the treatment. The dependent claims are included in this rejection.

Claim 12 lacks antecedent basis because the claim depends from claim 10 which recites "fibrosis due to pathological changes resulting from trauma" and claim 12 recites "fibrosis due to pathological changes resulting from trauma and surgical procedures" (see page 6 of the specification where this is outlined).

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-3 and 10 are rejected under 35 U.S.C 102(b) as being anticipated by Houck et al. (U.S. Patent No. 6,462,020, November 13, 1997).

Houck et al. teach a method to treat inflammation (pulmonary fibrosis) in a patient by administering a pharmaceutical composition comprising a peptide having the formula f-Met-Leu-X, wherein X is selected from the group consisting of Tyr, Tyr-Phe, Phe-Phe and Phe-Tyr (claims 1-3). Houck et al. disclose a method involving use of formyl peptides to treat asthma (inhaled dust particles, trauma) and rheumatoid arthritis (see claim 10 of the instant application and columns 1-2 of the reference). Thus, the limitations of the claims are met by this reference.

5. Claims 1-3 and 10 are rejected under 35 U.S.C. 102 (b) as being anticipated by Adamson et al. (Experimental Lung Research, vol. 20, no.3, pages 223-233, 1994).

Adamson et al. teach a method to treat pulmonary fibrosis by administering the peptide N-formyl-L-Methionyl-leucyl-phenylalanine. According to Adamson the pulmonary fibrosis occurs as a result of inhaled particles such as silica (trauma), see claim 10 of the instant application and page 223 of the reference. Therefore, the limitations of the claims are met by this reference.

### ***Conclusion***

6. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Hope A. Robinson whose telephone number is (703)308-6231. The Examiner can normally be reached on Monday - Friday from 9:00 A.M. to 5:30 P.M (EST).

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If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor Christopher S.F. Low, can be reached at (703)308-2932.

Any inquiries of a general nature relating to this application should be directed to the Group Receptionist whose telephone number is (703)308-0196.

Papers related to this application may be submitted by facsimile transmission. The official fax phone number for Technology Center 1600 is (703) 308-2742. Please affix the Examiner's name on a cover sheet attached to your communication should you choose to fax your response. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989).

Hope A. Robinson, MS 

Patent Examiner

  
CHRISTOPHER S. F. LOW  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600